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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,033	08/09/2005	Jean-Pierre Vors	P/3610-57	6764

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EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
02/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,033	VORS ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2008*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 2-11, 14, and 15 have been amended, Claims 16-19 have been added, and Claims 1, 12, and 13 have been cancelled by the Applicant in correspondence filed on 12/09/2008. Claims 2-11 and 14-19 are currently pending. This is the second Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

2. Claims 1-11 were objected to because of minor informalities. This objection is moot in light of Applicants' cancellation of Claim 1, amendments to Claims 2-11 and introduction of Claim 16.

3. Claims 1, 3, 4, 6, and 7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; specifically, the rejected claims contained a broad range together with a narrow range. This rejection is moot in light of Applicants' amendments to Claims 3, 4, 6, and 7 and cancellation of Claim 1.

4. Claims 7 8, 9, and 11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; specifically, there was insufficient antecedent basis for "compound II." This rejection is moot in light of Applicants' amendments to Claims 7, 8, 9, and 11.

5. Claims 6 and 13 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; specifically, it was unclear whether the rejected claims were to further comprise a specific species of compound II or a family of antifungals. This rejection is moot in light of Applicants' amendment to Claim 6 and cancellation of Claim 13.

6. Claims 12-15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; specifically the rejected claims were drawn to a use of a medicament without setting forth any steps involved in the method. This rejection is moot in light of Applicants' cancellation of Claims 12 and 13, and amendments to Claims 14 and 15.

7. Claims 12-15 were rejected under 35 U.S.C. 101 because the claimed recitation of a use of the claimed medicament. This rejection is moot in light of Applicants' cancellation of Claims 12 and 13, and amendments to Claims 14 and 15.

8. Claims 1-4 were rejected under 35 U.S.C. 102(b) as being anticipated by Charles, et al. (International Application WO 00/46184). This rejection is moot in light of Applicants' cancellation of Claim 1 and amendments to Claims 2-4.

9. Claims 1 and 5-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Charles, et al., in view of Bennett (Goodman & Gillman, The Pharmaceutical Basis of Therapeutics). This rejection is moot in light of Applicants' cancellation of Claim 1 and amendments to Claims 5-11.

10. Claim 5 was rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application Nos. 10/589,011 and 10/489,151.

The terminal disclaimer filed by Applicants on 12/09/2008 has been approved. Therefore, the rejection of Claim 5 is withdrawn.

11. Amended Claims 2-11, 14, and 15, and Claims 16-19 are examined on their merits and the following FINAL rejection is made.

12. Examiner noted a discrepancy between the amended Claims 14 and 15 filed on 12/09/2008, and the reply, also filed on 12/09/2008. Amended Claims 14 and 15 are drawn to a method of treating *Candida albicans* or *Aspergillus fumigatus*, respectively. The reply indicated that Claims 14 and 15 are drawn to a method of manufacture of the medicament (pg 19). Mr. Paul Grandinetti, the attorney of record, confirmed in telephone conversation of 02/18/2009, that Claims 14 and 15 as filed in the claim amendment are correct. Examiner notes that methods of manufacture would be a different invention.

Claim Rejections - 35 USC § 102

13. The text of 35 U.S.C. § 102(b) can be found in a prior Office action.

14. Claims 16, 2-5, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles, et al. (International Application No. WO 00/46184, already of record).

15. Newly added independent Claim 16 is drawn to a method for treating *Candida albicans* or *Aspergillus fumigatus* infections comprising administration of a medicament comprising at least one compound of formula (I). Claims 2 and 3 limit the substituents of Claim 16. Claim 4 limits formula (I) to 3 specific compounds. Claim 5 further limits the method such that the composition comprises an at least one additional antifungal compound. Claims 14 and 15 limit Claim 16 to specifically treat *C. albicans* and *A. fumigatus*, respectively.

16. Charles, et al., disclose an antifungal compound possessing the same number and identity of substituents claimed in the instant claims (pg 1, line 16 through pg 3, line 22). Preferred compounds disclosed in Charles, et al., (pg 3, line 24 through pg 4, line 14) correspond to the limitations of Claim 2. Especially preferred compounds of Charles, et al., correspond to the limitations of Claim 3, except that Charles, et al., "especially prefers" C_1-C_{10} alkyl, whereas Claim 3 is limited to C_1-C_6 alkyl. Compounds 364 and 365 (pg 46) correspond to N-ethyl-N-methyl-N'-[4-(4-chloro-3-trifluoromethylphenoxy)-2,5-dimethylphenyl]imidoformamide and N-ethyl-N-methyl-N'-[4-(4-fluoro-3-trifluoromethylphenoxy)-2,5-dimethylphenyl] imidoformamide, respectively, both of which are claimed in Claim 4. Charles, et al., explicitly contemplate treating fungal infestations in domestic and farm animals (pg 13, lines 32-33). Charles, et al., further teach that the compounds disclosed therein may be active against "general pathogens of . . . Ascomycete" (pg 10, lines 9-11). It is noted that both *C. albicans* and *A. fumigatus* belong to the phylum Ascomycota, and are thus considered Ascomycetes. Also, Charles, et al., teach the addition of a fungicide to the medicament (pg 10, lines 23-26). Examiner notes that Applicants admit in reply received on 12/09/2008 that the compositions described in Charles, et al., "can be used in the practice of the present invention" (pg 20, lines 16-17). Therefore, Charles, et al., anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

17. The text of 35 U.S.C. § 103 can be found in a prior Office action.

18. Claims 16, 5-11, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charles, et al., in view of Bennett (Goodman & Gillman, The Pharmaceutical Basis of Therapeutics, 10th ed., already of record).

19. Claim 16 is discussed above. Claim 5 further limits Claim 16 such that the medicament further comprises at least one other antifungal compound (II). Claim 6 limits the antifungal compound II to known antifungal families. Claims 7 and 9-11 limit the medicament to specific mass ratios (Claims 7 and 9), having a synergistic effect with compound I (Claim 8), further comprising a pharmaceutically acceptable excipient (Claim 10), and having compounds I and II comprise from 0.5-99% of the medicament (Claim 11). Claims 17-19 limit the method of treatment such that the medicament comprises one of the 3 compounds disclosed in Claim 4 and an antifungal selected from the group consisting of fluconazole and itraconazole.

20. Charles, et al., teach a method of treating *C. albicans* or *A. fumigatus* comprising administration of a composition comprising formula (I) in combination with an additional, generic antifungal agent. Charles, et al., do not teach a method combining compound I with another antifungal compound II, having a synergistic effect with a second compound, or further comprising a pharmaceutical excipient.

21. Both compound I and compound II are known to have antifungal effects (Charles, et al. [abstract], and Bennett [entire chapter], respectively. Bennett teaches that itraconazole can be used to treat candidiasis and aspergillosis (pg 1303-1304, "Therapeutic Uses"). Bennett also teaches that fluconazole can be used to treat candidiasis (pg 1305, "Therapeutic Uses. *Candidiasis*). Combining equivalents known for the same purpose is not a patentably distinguishing feature (MPEP §2173.05). "It is *prima facie* obvious to combine two

compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Optimizing the mass ratio of compounds I and II or adjusting the composition such that compounds I and II comprise 0.5-99% of the medicament is also not a patentably distinguishing feature (MPEP § 2144.05 II). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Finally, it is well known in the art to make medicaments comprising at least one excipient, which the FDA defines as substances other than the pharmacologically active drug or prodrug which are included in the manufacturing process or are contained in a finished pharmaceutical product dosage form. Examiner notes that Applicants admit in reply received on 12/09/2008 that the compositions described in Charles, et al., "can be used in the practice of the present invention" (pg 20, lines 16-17). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to modify the teachings of Charles, et al., to incorporate the teachings of Bennett to for the method of treating *C. albicans* or *A. fumigatus* infestations in animals comprising formula (I) (compound I) and a second antifungal compound (compound II).

Conclusion

22. Claims 2-11 and 14-19 are rejected.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625